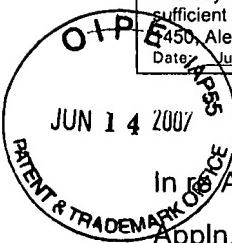


A.J. 3733  
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JUN 14 2007

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Appln. of: Kieran P. J. Murphy

Appln. No.: 09/594,685

Filed: June 16, 2000

For: APPARATUS FOR STRENGTHENING  
VERTEBRAL BODIES

Attorney Docket No: 8627/405 (PA-5281)

**BRINKS**  
**HOFER**  
**GILSON**  
**& LIONE**

Examiner: Michael J. Araj

Art Unit: 3733

Confirmation No. 2321

**Mail Stop Appeal Brief-Patents**  
Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

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**Attached is/are:**

- TRANSMITTAL OF SECOND SUBSTITUTE MAIN BRIEF ON APPEAL TO THE BOARD OF PATENT APPEALS AND INTERFERENCES (2 pages); and SECOND SUBSTITUTE MAIN BRIEF ON APPEAL TO THE BOARD OF PATENT APPEALS AND INTERFERENCES (52 pages).
- Return Receipt Postcard

**Fee calculation:**

- No additional fee is required.
- Small Entity.
- An extension fee in an amount of \$ \_\_\_\_\_ for a \_\_\_\_\_-month extension of time under 37 C.F.R. § 1.136(a).
- A petition or processing fee in an amount of \$ \_\_\_\_\_ under 37 C.F.R. § 1.17(\_\_\_\_\_.)
- An additional filing fee has been calculated as shown below:

|   | Claims Remaining<br>After Amendment |       | Highest No.<br>Previously Paid For | Present<br>Extra | Small Entity |           | Not a Small Entity |          |
|---|-------------------------------------|-------|------------------------------------|------------------|--------------|-----------|--------------------|----------|
|   |                                     |       |                                    |                  | Rate         | Add'l Fee | or                 | Rate     |
| Total                                     |                                     | Minus |                                    |                  | x \$25=      |           |                    | x \$50=  |
| Indep.                                    |                                     | Minus |                                    |                  | x 100=       |           |                    | x \$200= |
| First Presentation of Multiple Dep. Claim |                                     |       |                                    |                  | +\$180=      |           |                    | +\$360=  |
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Respectfully submitted,

Raymond W. Green (Reg. No. 24,587)

June 11, 2007

Date

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**BRINKS**  
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RAYMOND W. GREEN  
Registered Representative

Signature  
Date of Signature: June 11, 2007

### PATENT BHG&L Case 8627/405

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

|             |  |   |                           |
|-------------|--|---|---------------------------|
| Applicant:  | Kieran P. J. Murphy                                | : | Cook Case PA-5281         |
| Serial No.: | 09/594,685   | : | Confirmation No. 2321     |
| Filed:      | June 16, 2000                                      | : | Group Art Unit: 3733      |
| For:        | APPARATUS FOR<br>STRENGTHENING<br>VERTEBRAL BODIES | : | Examiner: Michael J. Araj |

### TRANSMITTAL OF SECOND SUBSTITUTE MAIN BRIEF ON APPEAL TO THE BOARD OF PATENT APPEALS AND INTERFERENCES

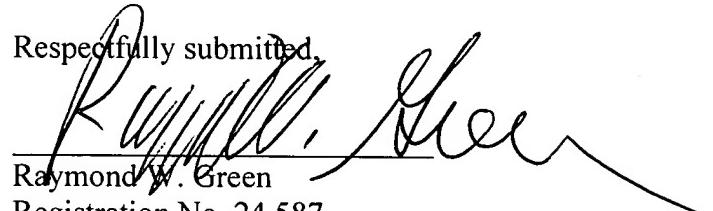
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COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, VA 22313-1450**

Sir:

Transmitted herewith is the SECOND SUBSTITUTE MAIN BRIEF ON APPEAL TO THE BOARD OF PATENT APPEALS AND INTERFERENCES. The fee under 37 CFR §41.20(b)(2) for filing an appeal brief has been paid previously.

However, in the event of underpayment or overpayment of any fee, please charge the deficit or credit the overpayment to the deposit account of Applicant's Attorneys, BRINKS HOFER GILSON & LIONE, Deposit Account No. 23-1925.

Respectfully submitted,

  
Raymond W. Green  
Registration No. 24,587

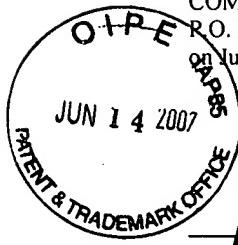
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June 11, 2007

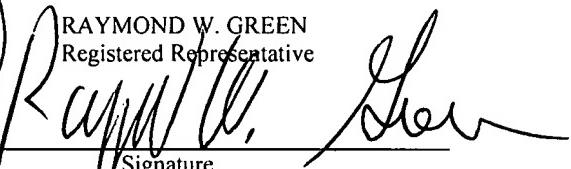
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Registered Representative

  
Signature

Date of Signature: June 11, 2007

**PATENT**

BHG&L Case 8627/405

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

|             |  |   |                           |
|-------------|--|---|---------------------------|
| Applicant:  | Kieran P. J. Murphy                                | : | Cook Case PA-5281         |
| Serial No.: | 09/594,685   | : | Confirmation No. 2321     |
| Filed:      | June 16, 2000                                      | : | Group Art Unit: 3733      |
| For:        | APPARATUS FOR<br>STRENGTHENING<br>VERTEBRAL BODIES | : | Examiner: Michael J. Araj |

**SECOND SUBSTITUTE MAIN BRIEF ON APPEAL TO THE  
BOARD OF PATENT APPEALS AND INTERFERENCES**

**Mail Stop Appeal Brief-Patents  
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P.O. Box 1450  
Alexandria, VA 22313-1450**

Sir:

**(1) REAL PARTY IN INTEREST**

The inventor has not assigned his entire interests in the invention, and hence a real party in interest is Applicant / Appellant Kieran P. J. Murphy. The inventor has, however, granted rights in the invention (not shown by documents of record in the Patent and Trademark Office) to Cook Incorporated of Bloomington, Indiana, which is another real party in interest.

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**(3) RELATED APPEALS AND INTERFERENCES**

There is no related pending or decided appeal or interference. A prior appeal in this Application resulted in prosecution being reopened on March 24, 2004, before an Examiner's Answer was written, and before transfer of the Application to the Board for consideration of the Appeal.

**(4) STATUS OF CLAIMS**

The claims presented are Claims 1-23. All claims are rejected. No claims have been cancelled. No claims have been allowed, although Claims 22 and 23 were indicated to be drawn to allowable subject matter. The rejection of all claims is appealed.

**(5) STATUS OF AMENDMENTS**

In response to the non-final Office Action of March 24, 2004, Applicant filed a timely Amendment on July 27, 2004, which has been entered. A copy of the claims submitted on July 27, 2004, omitting status indicators and claims not entered, is attached as Appendix A.

In response to a statement in the Final Rejection of November 15, 2004, that Claims 22 and 23 would be allowable if rewritten to overcome the rejection under 35 USC 112, second paragraph, and to include all of the limitations of the base claim and any intervening claims (Final Rejection, page 10), Applicant filed a proposed amendment to Claims 22 and 23 on February 10, 2005. An Advisory Action mailed on March 10, 2005, stated that the proposed Amendment filed February 10, 2005, would not be entered, because it was deemed to raise new issues that would require further consideration and/or search and because it was deemed to raise the issue of new matter; and that for purposes of appeal, the proposed amendment would not be entered and Claims 1-23 would continue to be rejected.

On April 5, 2005, Applicant filed a Request for Reconsideration of the denial of entry of the proposed Amendment filed February 10, 2005. No written Examiner response to this Request has been received. On May 9, 2005, a petition to review the denial of entry of the proposed Amendment filed February 10, 2005, was filed. On November 21, 2006, the petition was "dismissed" (so captioned, although the petition was considered on the merits and denied).

**(6) SUMMARY OF CLAIMED SUBJECT MATTER**

In the Claims filed July 27, 2004, and now appealed, Claims 1, 17, 20 and 21 are independent. In the Claims proposed February 10, 2005, but not entered, Claims 1, 17, 20, 21, 22 and 23 were independent. In a “Notification of Non-Compliant Appeal Brief” mailed May 24, 2007, the Patent Appeal Center Specialist requested descriptions reciting pages and line numbers and drawing reference characters for each of Claims 1, 17, 20, 21, 22 and 23.

**(a) Independent Claim 1 and Dependent Claims 2-16.**

The invention as claimed in Claim 1 is a tray (Figure 4, item 57 or item 59; Applicant’s Specification at page 5, line 16; page 9, line 20 and page 16, line 1 to page 17, line 16) of vertebroplasty components for use in performing vertebroplasty (surgery of the vertebrae), including a collection of components that Applicant has found to be useful for a surgeon intending to perform vertebroplasty.

The components recited in Claim 1 include:

a local anaesthesia assembly (Figure 4, item 61, Applicant’s Specification at page 5, lines 18-25; page 9, lines 21-23 and page 10, lines 19-23; which may include:

a local anaesthesia, Figure 4, item 63, Applicant’s Specification at page 5, lines 18-21 and page 9, lines 21-23;

a local anaesthesia aspiration syringe, Figure 4, item 65, Applicant’s Specification at page 5, lines 18-22;

a local anaesthesia aspiration needle, Figure 4, item 67, Applicant’s Specification at page 5, lines 18-20 and 22-23; and

a local anaesthesia injection needle, Figure 4, item 69, Applicant’s Specification at page 5, lines 18-20 and 22-23);

a bone cement assembly (Figure 4, item 80 or item 100, Applicant’s Specification at page 6, lines 12 to page 7, line 2; page 8, lines 12-18; page 9, line 28 to page 10, line 18; page 10, line 24 to page 12, line 3 and page 14, lines 1-3; which may include:

a container of a liquid monomer, Figure 4, item 82 or item 102, Applicant’s Specification at page 6, line 15; page 6, line 18 to page 7, line 2; page 7, lines 22-25 and page 8, lines 15-21;

a monomer aspiration syringe, Figure 4, item 84 or item 104, Applicant's Specification at page 6, lines 15-16 and page 7, lines 3-7 and page 8, lines 15-21; a monomer aspiration needle, Figure 4, item 85, Applicant's Specification at page 6, lines 15-16 and page 8, lines 15-21;

a mixing bowl, Figure 4, item 86 or item 106, Applicant's Specification at page 6, lines 15-16; page 7, lines 8-12 and page 8, lines 15-21;

a mixing spatula, Figure 4, item 88 or item 108, Applicant's Specification at page 6, lines 15-17; page 7, lines 10-12 and page 8, lines 15-21;

a container of polymer powder, Figure 4, item 90 or item 110, Applicant's Specification at page 6, lines 15-17; page 7, lines 15-25 and page 8, lines 15-21; and

an opacifier, Figure 4, item 92 or item 112, Applicant's Specification at page 6, lines 15-17; page 7, line 26 to page 8, line 11; page 8, line 22 to page 9, line 10 and page 11, line 23 to page 12, line 6);

a surgical cutting instrument such as a scalpel (Figure 4, item 71; Applicant's Specification at page 5, line 26 to page 6, line 2 and page 9, line 24, see also Claim 15); and

a device for injection of hardenable liquid biomaterial into a vertebral body, such as a vertebroplasty needle (Figure 4, item 73; Applicant's Specification at page 6, lines 3-11; page 9, lines 25-27, see also Claim 16).

Components recited in dependent claims 2-16, and which may be present in trays 57 and 59, include:

a container of a local anaesthesia (Claim 2: Figure 4, item 63; Applicant's Specification at page 5, lines 18-21 and page 9, lines 21-23);

a local anaesthesia aspiration syringe (Claim 3: Figure 4, item 65; Applicant's Specification at page 5, lines 18-22);

a local anaesthesia aspiration needle (Claim 4: Figure 4, item 67; Applicant's Specification at page 5, lines 18-20 and 22-23);

a local anaesthesia injection needle (Claim 5: Figure 4, item 69; Applicant's Specification at page 5, lines 18-20 and 22-23);

a container of a liquid monomer (Claim 6: Figure 4, items 82 and 102; Applicant's Specification at page 6, line 15; page 6, line 18 to page 7, line 2; page 7, lines 22-25 and page 8, lines 15-21);

a monomer aspiration needle (Claim 7: Figure 4, items 85 and 105; Applicant's Specification at page 6, lines 15-16 and page 8, lines 15-21);

a monomer aspiration syringe (Claim 8: Figure 4, items 84 and 104; Applicant's Specification at page 6, lines 15-16 and page 7, lines 3-7 and page 8, lines 15-21);

a mixing bowl (Claim 9: Figure 4, items 86 and 106; Applicant's Specification at page 6, lines 15-16; page 7, lines 8-12 and page 8, lines 15-21);

a mixing spatula (Claim 10: Figure 4, items 88 and 108; Applicant's Specification at page 6, lines 15-17; page 7, lines 10-12 and page 8, lines 15-21);

a container of polymer powder such as methylmethacrylate (Claims 11 and 13: Figure 4, items 90 and 110; Applicant's Specification at page 6, lines 15-17; page 7, lines 15-25 and page 8, lines 15-21); and

an opacifier (Claim 12: Figure 4, items 92 and 112; Applicant's Specification at page 6, lines 15-17; page 7, line 26 to page 8, line 11; page 8, line 22 to page 9, line 10 and page 11, line 23 to page 12, line 6).

No prior art reference or combination of references applied by the Examiner teaches or suggests the combinations of components claimed in claims 1-16.

**(b) Independent Claim 17 and Dependent Claims 18-19.**

The invention as claimed in Claim 17 is a vertebroplasty kit for use in performing vertebroplasty (Figure 4, item 55, Applicant's Specification at page 3, lines 3-7; page 5, lines 12-16; page 17, line 17 to page 18, line 8; page 20, lines 1-9). The vertebroplasty kit of Claim 17 comprises two trays (Figure 4, items 57 and 59; Applicant's Specification at page 5, line 16) of vertebroplasty components. The components may include:

a local anaesthesia assembly (Figure 4, item 61, Applicant's Specification at page 5, lines 18-25; page 9, lines 21-23 and page 10, lines 19-23; which may include:

a local anaesthesia, Figure 4, item 63, Applicant's Specification at page 5, lines 18-21 and page 9, lines 21-23;

a local anaesthesia aspiration syringe, Figure 4, item 65, Applicant's Specification at page 5, lines 18-22;

a local anaesthesia aspiration needle, Figure 4, item 67, Applicant's Specification at page 5, lines 18-20 and 22-23; and

a local anaesthesia injection needle, Figure 4, item 69, Applicant's Specification at page 5, lines 18-20 and 22-23);

a bone cement assembly (Figure 4, item 80 or item 100, Applicant's Specification at page 6, lines 12 to page 7, line 2; page 8, lines 12-18; page 9, line 28 to page 10, line 18 and page 10, line 24 to page 12, line 3; which may include:

- a container of a liquid monomer, Figure 4, item 82 or item 102, Applicant's Specification at page 6, line 15; page 6, line 18 to page 7, line 2; page 7, lines 22-25 and page 8, lines 15-21;
- a monomer aspiration syringe, Figure 4, item 84 or item 104, Applicant's Specification at page 6, lines 15-16 and page 7, lines 3-7 and page 8, lines 15-21;
- a monomer aspiration needle, Figure 4, item 85, Applicant's Specification at page 6, lines 15-16 and page 8, lines 15-21;
- a mixing bowl, Figure 4, item 86 or item 106, Applicant's Specification at page 6, lines 15-16; page 7, lines 8-12 and page 8, lines 15-21;
- a mixing spatula, Figure 4, item 88 or item 108, Applicant's Specification at page 6, lines 15-17; page 7, lines 10-12 and page 8, lines 15-21;
- a container of polymer powder, Figure 4, item 90 or item 110, Applicant's Specification at page 6, lines 15-17; page 7, lines 15-25 and page 8, lines 15-21; and
- an opacifier, Figure 4, item 92 or item 112, Applicant's Specification at page 6, lines 15-17; page 7, line 26 to page 8, line 11; page 8, line 22 to page 9, line 10 and page 11, line 23 to page 12, line 6);

a surgical cutting instrument such as a scalpel (Figure 4, item 71; Applicant's Specification at page 5, line 26 to page 6, line 2 and page 9, line 24); and

a device for injection of hardenable liquid biomaterial into a vertebral body, such as a vertebroplasty needle (Figure 4, item 73; Applicant's Specification at page 6, lines 3-11; page 9, lines 25-27).

The two trays of Claim 17 are arranged so that the first tray of components can be used to perform a first vertebroplasty injection through a first pedicle of a vertebral body (claim 17, lines 3-4), and then the second tray of components can either (a) be used to perform a second vertebroplasty injection through a second pedicle of a vertebral body, if it is determined that the first vertebroplasty injection did not sufficiently strengthen the vertebral body; or (b) remain sterile for use in another vertebral body if said first vertebroplasty injection is determined to have sufficiently strengthened the vertebral body (claim 17, lines 7-9). See Applicant's Specification at page 3, lines 2-7; page 10, line 11 to page 11, line 13; and page 20, lines 2-6.

Lazarus, the reference applied to allegedly anticipate Claims 17-19, does not teach 'vertebroplasty injection components' as recited in claim 17. Furthermore, no prior art reference or combination of references applied by the Examiner teaches or suggests the two-tray configuration claimed in claims 17-19, arranged so that the first tray of components can be used to perform a first vertebroplasty injection, and then the second tray of components can either (a) be used to perform a second vertebroplasty injection, or (b) remain sterile for use in another vertebral body.

**(c) Independent Claim 20.**

The invention as claimed in Claim 20 is a tray (Figure 4, item 57 or item 59; Applicant's Specification at page 5, line 16-25; page 6, lines 12 to page 7, line 2; page 8, lines 12-18; page 9, lines 20-23; page 9, line 28 to page 12, line 3; and page 18, lines 9-22) of vertebroplasty components for use in performing vertebroplasty, including a collection of components that Applicant has found to be useful for a surgeon intending to perform vertebroplasty.

Claim 20 recites the same ultimate components as Claim 1, but not the intermediate local anaesthesia assembly and bone cement assembly.

The components recited in Claim 20 include:

a local anaesthesia, Figure 4, item 63, Applicant's Specification at page 5, lines 18-21 and page 9, lines 21-23;

a local anaesthesia aspiration syringe, Figure 4, item 65, Applicant's Specification at page 5, lines 18-22;

a local anaesthesia aspiration needle, Figure 4, item 67, Applicant's Specification at page 5, lines 18-20 and 22-23;

a local anaesthesia injection needle, Figure 4, item 69, Applicant's Specification at page 5, lines 18-20 and 22-23;

a liquid monomer, Figure 4, item 82 or 102, Applicant's Specification at page 6, line 15; page 6, line 18 to page 7, line 2; page 7, lines 22-25 and page 8, lines 15-21;

a monomer aspiration needle, Figure 4, item 85 or 105, Applicant's Specification at page 6, lines 15-16 and page 8, lines 15-21;

a monomer aspiration syringe, Figure 4, item 84 or 104, Applicant's Specification at page 6, lines 15-16 and page 7, lines 3-7 and page 8, lines 15-21;

a mixing bowl, Figure 4, item 86 or 106, Applicant's Specification at page 6, lines 15-16; page 7, lines 8-12 and page 8, lines 15-21;

a mixing spatula, Figure 4, item 88 or 108, Applicant's Specification at page 6, lines 15-17; page 7, lines 10-12 and page 8, lines 15-21;

a polymer powder, Figure 4, item 90 or 110, Applicant's Specification at page 6, lines 15-17; page 7, lines 15-25 and page 8, lines 15-21;

an opacifier, Figure 4, item 92 or 112, Applicant's Specification at page 6, lines 15-17; page 7, line 26 to page 8, line 11; page 8, line 22 to page 9, line 10 and page 11, line 23 to page 12, line 6;

a scalpel, Figure 4, Figure 4, item 71; Applicant's Specification at page 5, line 26 to page 6, line 2 and page 9, line 24; and

a vertebroplasty needle, Figure 4, item 73; Applicant's Specification at page 6, lines 3-11; page 9, lines 25-27.

No prior art reference or combination of references applied by the Examiner teaches or suggests the combinations of components claimed in claim 20.

**(d) Independent Claim 21.**

The invention as claimed in Claim 21 is a tray (Figure 4, item 57 or item 59; Applicant's Specification at page 5, lines 16-25; page 9, line 20; and page 18, line 23, to page 19, line 8) of vertebroplasty components for use in performing vertebroplasty, including a collection of components that Applicant has found to be useful for a surgeon intending to perform vertebroplasty.

Claim 21 recites the same hardware components as Claim 1, but not the materials that are mixed to make the cement (monomer, polymer powder and opacifier).

The components include:

a local anaesthesia, Figure 4, item 63, Applicant's Specification at page 5, lines 18-21 and page 9, lines 21-23;

a local anaesthesia aspiration syringe, Figure 4, item 65, Applicant's Specification at page 5, lines 18-22;

a local anaesthesia aspiration needle, Figure 4, item 67, Applicant's Specification at page 5, lines 18-20 and 22-23;

a local anaesthesia injection needle, Figure 4, item 69, Applicant's Specification at page 5, lines 18-20 and 22-23;

a monomer aspiration needle, Figure 4, item 85 or 105, Applicant's Specification at page 6, lines 15-16 and page 8, lines 15-21;

a monomer aspiration syringe, Figure 4, item 84 or 104, Applicant's Specification at page 6, lines 15-16 and page 7, lines 3-7 and page 8, lines 15-21;

a mixing bowl, Figure 4, item 86 or 106, Applicant's Specification at page 6, lines 15-16; page 7, lines 8-12 and page 8, lines 15-21;

a mixing spatula, Figure 4, item 88 or 108, Applicant's Specification at page 6, lines 15-17; page 7, lines 10-12 and page 8, lines 15-21;

a scalpel, Figure 4, item 71; Applicant's Specification at page 5, line 26 to page 6, line 2 and page 9, line 24; and

a vertebroplasty needle, Figure 4, item 73; Applicant's Specification at page 6, lines 3-11; page 9, lines 25-27.

No prior art reference or combination of references applied by the Examiner teaches or suggests the combinations of components claimed in claim 21.

#### **(e) Dependent Claim 22.**

Claim 22 recites a vertebroplasty kit as claimed in Claim 17, but then also recites particular vertebroplasty components that are present in the kit.

The vertebroplasty kit of Claim 17 comprises two trays (Figure 4, items 57 and 59; Applicant's Specification at page 5, line 16) of vertebroplasty components.

The two trays of Claim 17 are arranged so that the first tray of components can be used to perform a first vertebroplasty injection through a first pedicle of a vertebral body (Claim 17, lines 3-4), and then the second tray of components can either (a) be used to perform a second vertebroplasty injection through a second pedicle of a vertebral body, if it is determined that the first vertebroplasty injection did not sufficiently strengthen the vertebral body; or (b) remain sterile for use in another vertebral body if said first vertebroplasty injection is determined to have sufficiently strengthened the vertebral body (Claim 17, lines 7-9). See Applicant's Specification at page 3, lines 2-7; page 10, line 11 to page 11, line 13; and page 20, lines 2-6.

The components recited in Claim 22 include:

a local anaesthesia, Figure 4, item 63, Applicant's Specification at page 5, lines 18-21 and page 9, lines 21-23;

a local anaesthesia aspiration syringe, Figure 4, item 65, Applicant's Specification at page 5, lines 18-22;

a local anaesthesia aspiration needle, Figure 4, item 67, Applicant's Specification at page 5, lines 18-20 and 22-23;

a local anaesthesia injection needle, Figure 4, item 69, Applicant's Specification at page 5, lines 18-20 and 22-23;

a liquid monomer, Figure 4, item 82 or 102, Applicant's Specification at page 6, line 15; page 6, line 18 to page 7, line 2; page 7, lines 22-25 and page 8, lines 15-21;

a monomer aspiration needle, Figure 4, item 85 or 105, Applicant's Specification at page 6, lines 15-16 and page 8, lines 15-21;

a monomer aspiration syringe, Figure 4, item 84 or 104, Applicant's Specification at page 6, lines 15-16 and page 7, lines 3-7 and page 8, lines 15-21;

a mixing bowl, Figure 4, item 86 or 106, Applicant's Specification at page 6, lines 15-16; page 7, lines 8-12 and page 8, lines 15-21;

a mixing spatula, Figure 4, item 88 or 108, Applicant's Specification at page 6, lines 15-17; page 7, lines 10-12 and page 8, lines 15-21;

a polymer powder, Figure 4, item 90 or 110, Applicant's Specification at page 6, lines 15-17; page 7, lines 15-25 and page 8, lines 15-21;

an opacifier, Figure 4, item 92 or 112, Applicant's Specification at page 6, lines 15-17; page 7, line 26 to page 8, line 11; page 8, line 22 to page 9, line 10 and page 11, line 23 to page 12, line 6;

a scalpel, Figure 4, item 71; Applicant's Specification at page 5, line 26 to page 6, line 2 and page 9, line 24; and

a vertebroplasty needle, Figure 4, item 73; Applicant's Specification at page 6, lines 3-11; page 9, lines 25-27.

See also Applicant's Specification at page 5, lines 18-25; page 6, lines 12 to page 7, line 2; page 8, lines 12-18; page 9, lines 21-23; and page 9, line 28 to page 12, line 3.

**(f) Dependent Claim 23.**

Claim 23 recites a vertebroplasty kit as claimed in Claim 17, but then also recites particular vertebroplasty components that are present in the kit. The vertebroplasty components recited in Claim 23 are a subset of the vertebroplasty components recited in Claim 22.

The vertebroplasty kit of Claim 17 comprises two trays (Figure 4, items 57 and 59; Applicant's Specification at page 5, line 16) of vertebroplasty components.

The two trays of Claim 17 are arranged so that the first tray of components can be used to perform a first vertebroplasty injection through a first pedicle of a vertebral body (claim 17, lines 3-4), and then the second tray of components can either (a) be used to perform a second vertebroplasty injection through a second pedicle of a vertebral body, if it is determined that the first vertebroplasty injection did not sufficiently strengthen the vertebral body; or (b) remain sterile for use in another vertebral body if said first vertebroplasty injection is determined to have sufficiently strengthened the vertebral body (claim 17, lines 7-9). See Applicant's Specification at page 3, lines 2-7; page 10, line 11 to page 11, line 13; and page 20, lines 2-6.

The components recited in Claim 23 include:

a local anaesthesia, Figure 4, item 63, Applicant's Specification at page 5, lines 18-21 and page 9, lines 21-23;

a local anaesthesia aspiration syringe, Figure 4, item 65, Applicant's Specification at page 5, lines 18-22;

a local anaesthesia aspiration needle, Figure 4, item 67, Applicant's Specification at page 5, lines 18-20 and 22-23;

a local anaesthesia injection needle, Figure 4, item 69, Applicant's Specification at page 5, lines 18-20 and 22-23;

a monomer aspiration needle, Figure 4, item 85 or 105, Applicant's Specification at page 6, lines 15-16 and page 8, lines 15-21;

a monomer aspiration syringe, Figure 4, item 84 or 104, Applicant's Specification at page 6, lines 15-16 and page 7, lines 3-7 and page 8, lines 15-21;

a mixing bowl, Figure 4, item 86 or 106, Applicant's Specification at page 6, lines 15-16; page 7, lines 8-12 and page 8, lines 15-21;

a mixing spatula, Figure 4, item 88 or 108, Applicant's Specification at page 6, lines 15-17; page 7, lines 10-12 and page 8, lines 15-21;

a scalpel, Figure 4, item 71; Applicant's Specification at page 5, line 26 to page 6, line 2 and page 9, line 24; and

a vertebroplasty needle, Figure 4, item 73; Applicant's Specification at page 6, lines 3-11; page 9, lines 25-27.

See also Applicant's Specification at page 5, lines 18-25; page 6, lines 12 to page 7, line 2; page 8, lines 12-18; page 9, lines 21-23; and page 9, line 28 to page 12, line 3.

No prior art reference or combination of references applied by the Examiner teaches or suggests the combinations of components claimed in Claim 22 or in Claim 23; and in fact the Examiner indicated in the Final Rejection mailed November 15, 2004, that Claims 22 and 23 were considered indefinite and rejected under 35 USC 112, second paragraph, in that it was unclear whether the recited components were present in the first and second tray in combination, or if each of the first and second trays contained the recited components; but that for examination purposes, the claims had been construed to recite that each of the first and second trays contained the recited components (page 2); and that Claims 22 and 23 would be allowable if rewritten to overcome the rejection under 35 USC 112, second paragraph, and to include all of the limitations of the base claim and any intervening claims (page 10).

**(7) GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL**

**(a)** Claims 22 and 23 are rejected as indefinite under 35 USC 112, second paragraph.

**(b)** Claims 17-19 are rejected as anticipated by Lazarus, U.S. Patent 4,128,173, under 35 USC 102(b).

**(c)** Claims 1-16, 20 and 21 are rejected as obvious in view of Vagley, U.S. 6,158,437, and also as obvious in view of Vagley in view of eleven secondary references (Shanley, U.S. 5,626,230; MacLeod et al., U.S. 5,506,257; Smith et al., U.S. 5,690,618; Arlers, U.S. 3,910,273; Racz, U.S. 5,817,074; Jiang et al., U.S. 5,847,046; Singer, U.S. 5,147,308; Draenert, U.S. 5,645,307; Haynie, U.S. 5,240,415; Hertzmann et al. U.S. 5,084,043; and Baker U.S. 4,554,686), under 35 USC 103(a).

**(8) ARGUMENT**

**(a) The Rejection of Claims 22 and 23 as Indefinite Should be Reversed,  
Because the Examiner's Interpretation is the Only Reasonable  
Interpretation.**

Claims 22 and 23 were rejected as indefinite under 35 USC 112, second paragraph, because the Examiner was not sure if the recited components were present collectively in both trays, or if each (the first and the second) tray contained the recited components; but that for examination purposes, the claims had been construed to recite that each of the first and second trays contained the recited components (Final Rejection of November 15, 2004, page 2).

It is submitted that the Examiner's interpretation is the only reasonable one, and that the Claims are not indefinite. If Applicant had intended to claim first and second trays that contained, in either Claim 22 or Claim 23, a first tray containing one set of components, and a second tray containing a second set of components, that would need to have been specified. Claims 22 and 23 recite, however, "... wherein the vertebroplasty injection components comprise ...". The antecedents of "the vertebroplasty injection components" are in both lines 3 and 5 of Claim 17.

If there were any doubt left after the grammatical analysis, the context makes it clear. The “first tray of vertebroplasty injection components” in Claim 17 is recited as “for performing a first vertebroplasty injection”. The “second tray of vertebroplasty injection components” in Claim 17 is recited as “for performing a second vertebroplasty injection through a second pedicle of said vertebral body, such that said second tray of vertebroplasty injection components can remain sterile for use in another vertebral body if said first vertebroplasty injection sufficiently strengthens said vertebral body”. So each tray needs to have what is needed “for performing a ... vertebroplasty injection”.

Claims 22 and 23 were proposed to be amended, to clarify that the components are those contained in each tray; however, the Examiner did not enter the proposed Amendment. The rejection should be reversed, because the interpretation chosen by the Examiner for the purpose of examination is the only reasonable one.

**(b) The Rejection of Claims 17-19 as Anticipated by Lazarus Should be Reversed, because Lazarus Does Not Teach ‘Vertebroplasty Injection Components’ as recited in claim 17.**

Claims 17-19 are rejected as anticipated by Lazarus, U.S. Patent 4,128,173. For the Lazarus patent to anticipate the claims, every element recited in these claims must be present in the Lazarus patent.

The Examiner does not take proper account of a point made in the Appeal Brief filed January 12, 2004, and reiterated in the last two Amendments, namely that the “Lazarus apparatus does not have ‘vertebroplasty injection components’, recited in claim 17, lines 3 and 5, in either tray.”

In construing terms in claims, the words used should be given their ordinary meaning to persons of ordinary skill in the art. Neither the Examiner nor the undersigned attorney is a person of ordinary skill in the art to which this invention pertains. The inventor, however, Dr. Kieran Murphy, is a person of more than ordinary skill in the art. Presented with the Amendment filed July 27, 2004, was a Declaration Under 37 CFR 1.132, explaining that the Lazarus apparatus does not have “vertebroplasty injection components”, recited in claim 17, lines 3 and 5, in either tray, as that term is understood by persons of ordinary skill in the art.

(See Declaration at pages 3-5, paragraphs 7-12.) A copy of the Declaration Under 37 CFR 1.132 is enclosed as Appendix B.

In response to Applicant's previous amendment and the Declaration Under 37 CFR 1.132, the Examiner repeats *verbatim* (Final Rejection of November 15, 2004, page 5) a paragraph from page 5 of the Office Action of March 24, 2004, concluding that "it is clear that each tray [of Lazarus] include[s] a[n] injection component and they can perform a function in spinal surgery if one so desire[s]." The Examiner ignores the explanation in the Declaration why the Lazarus components are not "vertebroplasty injection components", dismissing it as "opinion" of a party who has an interest in the outcome of the case, and lacking in "facts". The Examiner ignores the facts recited in the Declaration in Paragraphs 7-12, e.g., that vertebroplasty injection components are a different size than the Lazarus needles.

The Examiner then makes a point made previously, that the manner in which a device is to be employed does not differentiate the apparatus from prior art apparatus having the structural limitations. However, as explained in the Declaration, the recitation "vertebroplasty injection components" is more than an intended use; it designates for example needles sufficiently robust for injection of bone cement. The Examiner says "facts" are events, acts or occurrences which have actually taken place, and indeed, that is what *historical* facts are. However, it is also a fact, as pointed out in the Declaration, that vertebroplasty injection needles need to be sufficiently robust for injection of bone cement. So the Examiner ignores the facts stated in the Declaration, and *based on no facts at all*, elevates his own opinion over that of the expert. This is error.

With respect to the propriety of the Examiner or even the Board of Patent Appeals and Interferences elevating their own opinion over that of expert evidence of record, attention is directed to the recent precedential decision of the Court of Appeals for the Federal Circuit, *Brand v. Miller*, 82 USPQ2d 1705 (Fed. Cir. 2007). *Brand v. Miller* was the decision on appeal of *Miller v. Brand*, Interference 105,215. In that case, Miller alleged that Brand had derived the invention from Miller's drawings, MX 2001 and MX2002. "The Board described as 'unconvincing' the declaration of witness Bobby Deckard, who stated that 'there is no way one could deduce from [MX2001] how to build a machine [in accordance with the invention], because [MX2001] failed to explain why an artisan [would have known how to use and modify the devices shown in MX2002]' ". 82 USPQ2d at 1708. "The Board nonetheless held that Miller had established derivation based on the combination of MX2001 and 2002." 82 USPQ2d

at 1708. The Court held “that, in the context of a contested case, it is impermissible for the Board to base its factual findings on its expertise, rather than on the evidence in the record, although the Board’s expertise appropriately plays a role in interpreting record evidence.” 82 USPQ2d at 1710. The Court went on to say “We do not – and need not – decide here the extent to which the Board in ex parte proceedings is so limited.” 82 USPQ2d at 1710. The Examiner has not, however, explained why the Examiner should base his factual findings (that “it is clear that each tray [of Lazarus] include[s] a[n] injection component and they can perform a function in spinal surgery if one so desire[s].”) on his expertise, rather than on the evidence in the record (the explanation in the Declaration why the Lazarus components are not “vertebroplasty injection components”).

The Examiner points out (Final Rejection of November 15, 2004, page 7) that some of the items recited in Applicant’s claims are general surgical apparatus. The claims were proposed to be amended accordingly, even though the amendment was not deemed to be necessary, and was not deemed to change the scope of the Claims. Other items recited in Applicant’s claims, however, are vertebroplasty components, not taught or suggested by the applied references.

Accordingly, the rejection of Claims 17-19 should be reversed.

**(c) The Rejections of Claims 1-16, 20 and 21 as Obvious from Vagley or from Vagley in View of Eleven Other References Should be Reversed, Because the Prior Art does not Teach or Suggest the *Combinations* Claimed in Claims 1-16, 20 and 21.**

Claims 1-16, 20 and 21 are rejected as obvious in view of Vagley, U.S. 6,158,437, and also as obvious in view of Vagley in view of eleven secondary references (Shanley, MacLeod et al., Smith et al., Arlers, Racz, Jiang et al., Singer, Draenert, Haynie, Hertzmann et al. and Baker).

The Examiner has used Applicant’s claims as a shopping list to find patents that teach each *element* (or something he considers to be *like* each element) in the combination, but has not cited or applied a reference that teaches or suggests the *combination* itself.

Claims 1-16, 20 and 21 are directed to trays of vertebroplasty and surgical components for use in performing vertebroplasty. The Vagley patent discloses a tray and says things *other than* vertebroplasty components should be on the tray. So Vagley does not teach or suggest *Applicant’s* combination, Vagley teaches a *different* combination.

The Declaration Under 37 CFR 1.132, a copy of which is Appendix B, explains why the *combinations* claimed in Claims 1-16, 20 and 21 would not have been obvious to a person of ordinary skill in the art, either from Vagley alone or from Vagley in view of the eleven secondary references applied in another rejection. (See Declaration at page 5, paragraphs 13-14.)

In response to Applicant's previous amendment and the Declaration, the Examiner says (pages 8-9 of Final Rejection) that Vagley discloses that his tray can be customized to cater to the preference of a specific surgeon. This does not amount to a teaching or suggestion of the *particular combinations* claimed by Applicant.

Accordingly, the rejections of Claims 1-16, 20 and 21 should be reversed.

## (9) CONCLUSION

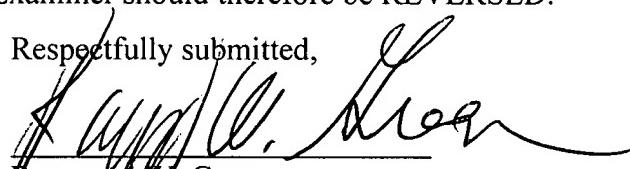
Claims 17-19, 22 and 23 recite "vertebroplasty injection components", which are not present in the Lazarus patent. Applicant has filed the Declaration Under 37 CFR 1.132 of the inventor, Dr. Kieran Murphy, showing that the Lazarus patent does not teach "vertebroplasty injection components" as that term is understood by persons of ordinary skill in the art.

Claims 1-16, 20 and 21 recite combinations, which neither Vagley nor any of the secondary references teach or suggest.

Claims 22 and 23 were indicated to be allowable if rewritten to overcome formal rejections and eliminate reference to rejected claims. Claims 22 and 23 were proposed to be amended to overcome formal rejections and eliminate reference to rejected claims, but have not been allowed. Nevertheless, the construction for examination purposes, that each of the first and second trays contained the recited components (Final Rejection of November 15, 2004, page 2), is the only reasonable one.

Accordingly, the Application appears to be in order for allowance, both as to form and in view of the prior art. All rejections applied by the Examiner should therefore be REVERSED.

Respectfully submitted,

  
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June 11, 2007

**(10) APPENDIX A – Claims presented July 27, 2004**

1. A tray of vertebroplasty components for use in performing vertebroplasty, said tray comprising:

a local anaesthesia assembly for producing a reversible loss of sensation in a surgical area proximate to a vertebral body;

a bone cement assembly for preparation of a hardenable liquid biomaterial for strengthening said vertebral body;

a surgical cutting instrument for providing cutaneous incision in said surgical area proximate to said vertebral body; and

a device for injection of said hardenable liquid biomaterial into said vertebral body.

2. The tray according to claim 1, wherein said local anaesthesia assembly includes at least one container of a local anaesthesia.

3. The tray according to claim 1, wherein said local anaesthesia assembly includes at least one local anaesthesia aspiration syringe.

4. The tray according to claim 1, wherein said local anaesthesia assembly includes at least one local anaesthesia aspiration needle.

5. The tray according to claim 1, wherein said local anaesthesia assembly includes at least one local anaesthesia injection needle.

6. The tray according to claim 1, wherein said bone cement assembly includes at least one container of a liquid monomer.

7. The tray according to claim 1, wherein said bone cement assembly includes at least one monomer aspiration needle.

8. The tray according to claim 1, wherein said bone cement assembly includes at least one monomer aspiration syringe.

9. The tray according to claim 1, wherein said bone cement assembly includes at least one mixing bowl.

10. The tray according to claim 1, wherein said bone cement assembly includes at least one mixing spatula.

11. The tray according to claim 1, wherein said bone cement assembly includes at least one container of polymer powder.

12. The tray according to claim 1, wherein said bone cement assembly includes an opacifier.

13. The tray according to claim 11, wherein said polymer powder is methylmethacrylate.

14. The tray according to claim 11, wherein said polymer powder in said hardenable liquid biomaterial is from about five grams to about forty grams of methylmethacrylate.

15. The tray according to claim 11, wherein said surgical cutting instrument is a scalpel.

16. The tray according to claim 11, wherein said device for injection is a vertebroplasty needle.

17. A vertebroplasty kit for use in performing vertebroplasty, said vertebroplasty kit comprising:

a first tray of vertebroplasty injection components for performing a first vertebroplasty injection through a first pedicle of a vertebral body;

a second tray of vertebroplasty injection components for performing a second vertebroplasty injection through a second pedicle of said vertebral body, such that said second tray of vertebroplasty injection components can remain sterile for use in another vertebral body if said first vertebroplasty injection sufficiently strengthens said vertebral body.

18. The kit according to claim 17, wherein said first tray and said second tray are individually assembled and packaged.

19. The kit according to claim 18, wherein said first tray and said second tray are sterile until use in performing vertebroplasty.

20. A tray of vertebroplasty components for use in performing vertebroplasty, said tray comprising:

- a local anaesthesia;
- a local anaesthesia aspiration syringe;
- a local anaesthesia aspiration needle;
- a local anaesthesia injection needle;
- a liquid monomer;
- a monomer aspiration needle;
- a monomer aspiration syringe;
- a mixing bowl;
- a mixing spatula;
- a polymer powder;
- an opacifier;
- a scalpel; and
- a vertebroplasty needle.

21. A tray of vertebroplasty components for use in performing vertebroplasty, said tray comprising:

- a local anaesthesia;
- a local anaesthesia aspiration syringe;

a local anaesthesia aspiration needle;  
a local anaesthesia injection needle;  
a monomer aspiration needle;  
a monomer aspiration syringe;  
a mixing bowl;  
a mixing spatula;  
a scalpel; and  
a vertebroplasty needle.

22. The kit according to claim 17, wherein the vertebroplasty injection components comprise:

a local anaesthesia;  
a local anaesthesia aspiration syringe;  
a local anaesthesia aspiration needle;  
a local anaesthesia injection needle;  
a liquid monomer;  
a monomer aspiration needle;  
a monomer aspiration syringe;  
a mixing bowl;  
a mixing spatula;  
a polymer powder;  
an opacifier;  
a scalpel; and  
a vertebroplasty needle.

23. The kit according to claim 17, wherein the vertebroplasty injection components comprise:

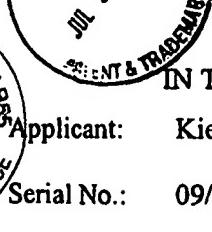
a local anaesthesia;  
a local anaesthesia aspiration syringe;  
a local anaesthesia aspiration needle;  
a local anaesthesia injection needle;

a monomer aspiration needle;  
a monomer aspiration syringe;  
a mixing bowl;  
a mixing spatula;  
a scalpel; and  
a vertebroplasty needle.

**(11) APPENDIX B – EVIDENCE APPENDIX**

Appended hereto as pages 25-51 is a copy of the Declaration Under 37 CFR 1.132 by Kieran P. J. Murphy signed July 26, 2004, and of record in this Application file (filed July 27, 2004).

With respect to 37 CFR 41.37(c)(1)(ix), in the Final Rejection mailed November 15, 2004, in this Application, the Examiner states that the Murphy Declaration was considered (page 6).



PATENT  
BHG&L Case 8627/405

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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TECHNOLOGY CENTER R3700

Applicant: Kieran P. J. Murphy : Cook Case PA-5281  
Serial No.: 09/594,685 :  
Filed: June 16, 2000 : Group Art Unit: 3732  
For: METHOD AND APPARATUS : Examiner: Eduardo C. Robert  
FOR STRENGTHENING  
VERTEBRAL BODIES :

DECLARATION UNDER 37 CFR 1.132

KIERAN P. J. MURPHY declares as follows:

1. I am the sole inventor of this Application. I am a medical doctor, graduated from The Royal College of Surgeons in Ireland, Dublin, Ireland. I am licensed to practice medicine in Maryland, license No. D0054096, and was previously licensed to practice medicine in Michigan and New York. I am a practicing surgeon, and I typically perform dozens of surgical procedures in a week. I have performed over 500 vertebroplasty injection surgeries.

2. I have been a professional Lecturer in Neuroradiology in the Department of Radiology of the Veterans Administration Center in Ann Arbor, Michigan; Lecturer in Neuroradiology in the Department of Radiology of The University of Michigan in Ann Arbor, Michigan; Assistant Professor of Radiology, Section Chief of Neuroradiology, Director of Interventional & Therapeutic Neuroradiology, and Director of Radiology Research in Albany Medical College, Albany, New York; Assistant Professor of Radiology and Neurological Surgery and Director of Interventional Neuroradiology in the Division of Neuroradiology of Johns Hopkins University, School of Medicine, Baltimore, Maryland. I am presently Associate Professor of Radiology and Neurological Surgery and Director of Interventional Neuroradiology at Johns Hopkins University, School of Medicine. I have authored or co-authored 77 peer-reviewed articles, 11 review articles, and three published letters for professional medical journals. I have authored three chapters of published books. I am named as sole or joint inventor in a number of patents and pending patent applications, including the following:

- a. Murphy U.S. Patent 6,273,916, *Method and Apparatus for Strengthening Vertebral Bodies*, issued August 14, 2001;
- b. Murphy U.S. Patent 6,450,973, *Biopsy Gun*, issued September 17, 2002;
- c. Murphy U.S. Patent 6,488,677, *Needle Control Device*, issued December 3, 2002;
- d. Cowan et al. U.S. Patent 6,585,677, *Shunt*, issued July 1, 2003;
- e. Murphy U.S. Patent 6,749,595, *Cement Delivery Needle*, issued June 15, 2004;
- f. Murphy et al. U.S. Patent 6,752,791, *Needle Control Device*, issued June 22, 2004;
- g. Murphy et al. U.S. Patent Application Publication US 2003/0181807, *Method, Device and System for Implanting a Shunt*, published September 25, 2003;
- h. Murphy U.S. Patent Application Publication US 2003/0204248, *Device Viewable under an Imaging Beam*, published October 30, 2003;
- i. Anderson et al. U.S. Patent Application Publication US 2004/0009459, *Simulation System for Medical Procedures*, published January 15, 2004;
- j. Cowan et al. U.S. Patent Application Publication US 2004/0030278, *Shunt*, published February 12, 2004; and
- k. Murphy et al. U.S. Patent Application Publication US 2004/0070253, *Surgical Chair for Percutaneous Spinal Catheter Insertion*, published April 15, 2004.

3. Recent articles co-authored by me include the following:

- a. Alan Hammond, Lee H. Riley III, Philippe Gailloud, David A. Nussbaum, Monica Watkins, and Kieran J. Murphy, "Treatment Considerations for Vertebroplasty in Men," *AJNR Am J Neuroradiol* 25:639-641, April 2004.
- b. Doris D. M. Lin, MD, PhD, Philippe Gailloud, MD, and Kieran J. Murphy, MD, FRCPC, "Percutaneous Vertebroplasty in Benign and Malignant Disease," *Nurosurgery Quarterly*, 11(4):290-301, 2001.
- c. Kieran J. Murphy, MD, FRCPC, and Doris D. M. Lin, MD, PhD, "Vertebroplasty: A Simple Solution to a Difficult Problem," *Journal of Clinical Densitometry*, 4(3): 189-197, Fall 2001.
- d. David A. Nussbaum, MS, Philippe Gailloud, MD, and Kieran Murphy, MD, "The Chemistry of Acrylic Bone Cements and Implications for Clinical Use in Image-guided Therapy," *J Vasc Interv Radiol* 15:121-26, February 2004.

e. Cristiana Vasconcelos, Philippe Gailloud, Norman J. Beauchamp, Donald V. Heck, and Kieran J. Murphy, "Is Percutaneous Vertebroplasty without Pretreatment Venography Safe? Evaluation of 205 Consecutive Procedures," *AJNR Am J Neuroradiol*, 23:913-917, June/July 2002.

4. A copy of my *curriculum vitae* is attached to this Declaration.

5. I have been requested to give the expert opinions expressed below in this Declaration. I believe I am qualified, by education and experience, to do so.

6. I have been advised that Claims 1-21 of my pending patent application Serial No. 09/594,685, filed June 16, 2000, for METHOD AND APPARATUS FOR STRENGTHENING VERTEBRAL BODIES, have been rejected in an Office Action dated March 24, 2004, hereinafter the "Office Action". I am advised that in one element of this rejection, the Examiner rejects my Claims 17-19 as anticipated by Lazarus, U.S. Patent 4,128,173. I understand that for the Lazarus patent to anticipate my claims, every element recited in these claims must be present in the Lazarus patent. I am of the opinion that Lazarus does not show *vertebroplasty injection components* which I recite in Claim 17, lines 3 and 5.

7. The Examiner comments at page 5 of the Office Action, that Lazarus's tray 10b includes a syringe (item 36 in his drawings) and needle (item 38); and the Examiner alleges that Lazarus's syringe and needle are capable of being used in a spinal surgical procedure, e.g., for injecting anesthesia [*i.e.*, an anesthetic]. I understand that terms in a patent or patent application, such as "vertebroplasty injection components", are given the ordinary meaning of those terms to *persons of ordinary skill in the art*, such as a surgeon performing a vertebroplasty injection. I am of the opinion that Lazarus' syringe and needle are NOT *vertebroplasty injection components*. While it is true that Lazarus's syringe and needle are capable of injecting anesthetic, including doing so into the spine, injecting anesthetic into the spine is not vertebroplasty injection, and a syringe and needle for injecting anesthetic are not vertebroplasty injection components, but rather general surgical apparatus.

8. Lazarus's needles are thin-walled and not suitable for vertebroplasty injection. A bone-cement injection needle suitable for vertebroplasty injection is much more robust (typically eleven gauge or thirteen gauge, see my Application at page 6, lines 3-6, although sometimes a 14

gauge needle would be used) than the needles described by Lazarus (26 gauge, see Lazarus at column 1, lines 37-39). Bone-cement injection needles are used as agents of delivery of bone cement, and they must be sturdy enough to do the job.<sup>1</sup>

9. The Examiner alleges further that "Lazarus's tray 10a includes a cannula for injecting or aspirating fluid and it is capable of being used in a spinal surgical procedure, e.g. for injecting or aspirating nucleus pulposus [sic]." (Office Action at page 5.) This comment appears to be based on Lazarus at Figure 1 and column 3, lines 6-8, "FIG. 1 illustrates a package 10 containing ... an elongated cannula 16." Lazarus's cannula 16 is smaller than one millimeter, see Lazarus at column 3, lines 54-57 (1 millimeter incision is slightly longer than the diameter of cannula 16) and column 4, lines 52-55 (Becton-Dickinson 18G23/4 thin wall catheter is preferred). In my opinion, in making the statement just quoted, the Examiner is mistaken on two counts. First, Lazarus's preferred Becton-Dickinson 18G23/4 thin wall catheter cannula 16 would be too small for injecting or aspirating nucleus pulposus (the central portion of intervertebral disks, consisting of a pulpy elastic substance, to which the Examiner apparently intended to make reference). Secondly, while injecting or aspirating nucleus pulposus may be a spinal surgical procedure, it is not vertebroplasty injection, and a cannula for injecting or aspirating nucleus pulposus is not a vertebroplasty injection component.

10. The Examiner alleges further that "each [Lazarus] tray include[s] a[n] injection component and they can perform a function in spinal surgery if one so desires." (Office Action at page 5.) In my opinion, in making the statement just quoted, the Examiner is mistaken on two counts. First, the Lazarus components are not suitable for performing spinal surgery. Secondly, a spinal surgical procedure is not necessarily a vertebroplasty injection, and components for performing spinal surgery are not necessarily vertebroplasty injection components.

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<sup>1</sup> Medical needles' diameters are usually referred to by Gauge numbers according to the Stub's Needle Gauge System, according to which a Gauge 11 needle has an outside diameter of 0.1190 to 0.1210 inches, a Gauge 13 needle has an outside diameter of 0.0940 to 0.0960 inches, a Gauge 14 needle has an outside diameter of 0.0820 to 0.0840 inches, and a Gauge 26 needle has an outside diameter of 0.0180 to 0.0185 inches. Inside diameters depend on wall thicknesses, and can range from about 0.0920 to about 0.1060 inches for Gauge 11, from about 0.0690 to about 0.0830 inches for Gauge 13, from about 0.0610 to about 0.0730 inches for Gauge 14, and from about 0.0095 to about 0.0110 inches for Gauge 26.

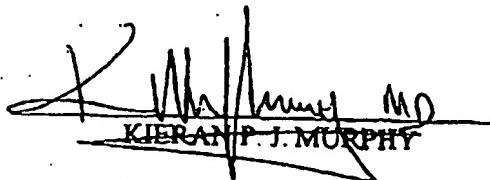
11. The Examiner alleges further that "the Lazarus kit has the ability to perform the functional language of the claim." (Office Action at page 5.) In my opinion, in making the statement just quoted, the Examiner is mistaken. My Claim 17 recites "performing a first vertebroplasty injection through a first pedicle of a vertebral body;" and "performing a second vertebroplasty injection through a second pedicle of said vertebral body". In my opinion, the Lazarus kit does NOT have the ability to perform a first vertebroplasty injection through a first pedicle of a vertebral body; or to perform a second vertebroplasty injection through a second pedicle of the vertebral body.

12. The Examiner asserts, incorrectly in my opinion, that a surgeon would use the peritoneal fluid treatment components disclosed by Lazarus in performing a vertebroplasty injection. In my opinion, the syringe, needle and cannula that Lazarus discloses are not "vertebroplasty injection components", but rather general surgical or peritoneal fluid treatment components. In my opinion, just because a surgeon would use some type of syringe, needle and cannula in vertebroplasty injection, does not mean that he or she would use the peritoneal fluid treatment components disclosed by Lazarus in performing a vertebroplasty injection.

13. I am advised that in one element of the March 24, 2004, rejection of the claims of my Application, the Examiner rejects my Claims 1-16, 20 and 21 as unpatentable over (obvious in view of) Vagley U.S. Patent 6,158,437; or as obvious from Vagley in view of 11 other references (Office Action, pages 4-5). I understand that for the Vagley patent to render my claims obvious, the Examiner must show each element of the claimed combination, as well as a teaching or suggestion to make the claimed combination.

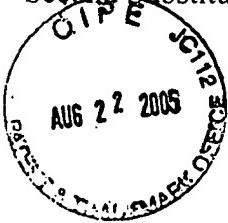
14. I have reviewed the Vagley Patent. Vagley describes a rhinoplasty kit for plastic surgery (nose jobs). None of Vagley's components can be used for vertebroplasty. There is no vertebroplasty needle. There is no mixing bowl or spatula or bone cement. The Vagley Patent is directed to a tray of rhinoplasty components and their arrangement in order of use during rhinoplasty. Vertebroplasty is a different procedure, and it uses different components. In my opinion, neither the Vagley Patent alone, nor the Vagley Patent in combination with the 11 other references upon which the Examiner relies, would suggest to a person of ordinary skill in the art, the combinations claimed in my Claims 1-16, 20 and 21.

15. I further declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and I am warned that willful false statements and the like are punishable by fine or imprisonment, or both (18 U.S.C. 1001) and may jeopardize the validity of the application or any patent issuing thereon.



KIERAN P. J. MURPHY

Date signed: July 26, 2004



**CURRICULUM VITAE**  
**The Johns Hopkins University School of Medicine**

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Kieran P.J. Murphy, MB. BCH., FRCPC

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04/27/04

Date Revised

**DEMOGRAPHIC INFORMATION**

**Current Appointments**

Associate Professor

The Johns Hopkins University School of Medicine  
Joint Appointment, Russell H. Morgan Department  
of Radiology and Department of Neurosurgery

Director of Interventional Neuroradiology      The Johns Hopkins University School of Medicine

**Personal Data**

Home Address:

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**Education and Training**

Graduate:

1980-1986    M.B. B.Ch.,BAO, LRCPI, LRCSI.(Hons).  
The Royal College of Surgeons in Ireland, Dublin, Ireland

1987-1988    B.Sc. in Anatomy, Embryology and Physical Anthropology (First Place)  
University College, Dublin, Ireland

Postdoctoral:

1986-1987    General Internship in the Professorial Unit (6 months surgery/medicine): The  
Charitable Infirmary, Jervis Street Teaching Hospital of the Royal College of  
Surgeons, Dublin, Ireland

1987-1988    Lecturer in Anatomy, Department of Anatomy, The Royal College of Surgeons,  
Dublin, Ireland

1987-1988    Surgical house officer St. Joseph's Hospital, Raheny, Dublin, Ireland.

1989 General Surgery Training Scheme, Department of Surgery, Beaumont Hospital, Dublin, Ireland.  
1989-1990 General Medicine Internship, Albany Medical Center, Albany, New York.  
1990-1993 Radiology Residency, Department of Radiology, Albany Medical Center, Albany, New York.  
1993-1994 Radiology Residency, Department of Radiology, University of Michigan Medical Center, Ann Arbor, Michigan  
1994-1996 Neuroradiology Fellowship, Division of Neuroradiology, Department of Radiology, University of Michigan Medical Center, Ann Arbor, Michigan.  
1996-1997 Interventional Neuroradiology (Mentor: Prof. Rüfenacht) Division of Neuroradiology, Department of Radiology, Hospital Cantonal, University of Geneva, Geneva, Switzerland.

**Professional Experience**

1995-1996 Lecturer in Neuroradiology, Department of Radiology Veterans Administration Medical Center, Ann Arbor, Michigan.  
1995-1996 Lecturer in Neuroradiology, Department of Radiology, University of Michigan Medical Center, Ann Arbor, Michigan.  
1997-1998 Assistant Professor of Radiology, Section Chief of Neuroradiology and Director of Interventional & Therapeutic Neuroradiology, Albany Medical College, Albany, New York.  
1997-1998 Director of Radiology Research, Albany Medical College, Albany, New York  
1998-2000 Assistant Professor of Radiology and Neurological Surgery, Director of Interventional Neuroradiology, Division of Neuroradiology, Johns Hopkins University, School of Medicine.  
2000-present Associate Professor of Radiology and Neurological Surgery, Director of Interventional Neuroradiology, Johns Hopkins University, School of Medicine.

**RESEARCH ACTIVITIES**

**Publications**

**Peer-Reviewed Articles**

1. Murphy K. Planting mangoes for the future in Tibet. *British Medical Journal*. 1986; 293:1649-1652.
2. Murphy KJ, MacFarlane DJ, Shulkin BL. FDG PET imaging of paragangliomas of the neck: Comparison with MIBG SPECT. *European Journal of Nuclear Medicine* 1995; 22(11):1347-1350.
3. Murphy K, Brunberg JA. Images in clinical medicine. Miliary tuberculosis in the central nervous system. *N Engl J Med* 1996; 334(12):769.
4. Murphy KJ, Brunberg JA. Evaluation of the history of injury as the threshold for screening orbital plain films prior to MRI. *American Journal of Roentgenology* 1996; 167:847-849.
5. Murphy KJ, Brunberg JA, Cohan RH. Contrast reactions associated with gadolinium chelate administration. *American Journal of Roentgenology* 1996; 167:1053-1055.

6. Murphy KJ, Kazerooni EA, Weinberg E, Killam D, Hendrick WJ, Braun M. The radiographic presentation of the intrathoracic complications of pregnancy *Can Assoc Radiol.* 1996 Dec; 47.
7. Murphy KJ. Radiology in Nepal. *American Journal of Roentgenology.* 1996; 167:1593-1594.
8. Murphy KJ. Recharging the batteries; Primary health care for Tibetan refugees. *British Medical Journal.* 1996;313:1644-6.
9. Murphy KJ, Cloft HJ, Prince M. 3D gadolinium-enhanced MR angiography of the carotid arteries. *Magnetic Resonance Imaging.* 1997; 14(6):593-600.
10. Murphy KJ, Brunberg JA. Claustrophobia and sedation in MRI. *Magnetic Resonance Imaging.* 1997; 15(1):51-54.
11. Murphy KJ, Rubin JA. Power Doppler "It's a Good Thing." *Seminars in US, CT and MRI.* 1997; 18(1):13-21.
12. Hilborn M, Murphy KJ, Bude RO, Platt JF, Rubin JM. Renal transplant rejection evaluation with power Doppler sonography. *British Journal of Radiology.* 1997; 70:39-42.
13. Murphy KJ, Hansen R, Prince M. Case report. Cutaneous pain and thromboplebitis after gadolinium contrast injection. *American Journal of Radiology.* 1997; 169:318-319.
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19. Murphy KJ, Beydoun A, Brunberg JA, Jamadar DA, Frey KA. Correlation of Continuous EEG Monitoring with [O-15]H<sub>2</sub>O Positron Emission Tomography Determination of Cerebral Blood Flow during Balloon Test Occlusion of the Internal Carotid Artery . Experience in 32 cases. *Interventional Neuroradiology.* 1998; 4:51-55.
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55. Clatterbuck RE, Cohen B, Gailloud P, Murphy K, Rigamonti D. Vertebral hemangiomas associated with familial cerebral cavernous malformation: segmental disease expression. Case report. *J Neurosurgery*. 2002 Sep; 97(2 Suppl):227-30.
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71. Gailloud P, Carpenter J, Heck DV, Murphy KJ. Pseudofenestration of the Cervical Internal Carotid Artery: A Pathologic Process that Simulates an Anatomic Variant. *AJNR Am J Neuroradiol.* 2004 Mar;25:421-424.
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73. Gailloud P, Oishi S, Carpenter J, Murphy KJ. Three-Dimensional Digital Angiography: New Tool for Simultaneous Three-Dimensional Rendering of Vascular and Osseous Information during Rotational Angiography. *AJNR Am J Neuroradiol.* 2004 Apr;25(4):571-3.

74. Goldenberg-Cohen N, Curry C, Miller NR, Tamargo RJ, Murphy KJ. *Journal of Neurology, Neurosurgery, and Psychiatry.* (2004, in press).
75. Gailloud P, Clatterbuck RE, Fasel JHD, Tamargo RJ, Murphy KJ. Segmental agenesis of the internal carotid artery distal to the posterior communicating artery leading to the definition of a new embryologic segment. *AJNR Am J Neuroradiol.* (2004, in press).
76. Subramanian PS, Gailloud PH, Heck DV, Tamargo RJ, Murphy KJ, Miller, NR. Guglielmi Detachable Coil Embolization of a Symptomatic, Isolated Orbital Arteriovenous Fistula via a Superior Ophthalmic Vein Approach. *Neuroradiology.* (2004, in press).
77. Nussbaum D, Gailloud P, Murphy K. Vertebroplasty and Kyphoplasty Complications Reported to FDA Website. *Journal of Vascular and Interventional Radiology.* (2004, in press).

*Review Articles*

1. Rapoport R, Murphy KJ. Clinical experience with a superconducting 0.35T Open MRI system. *Toshiba Medical Review.* 1999; 69.
2. Murphy KJ, Deramond H. Vertebroplasty in Benign and Malignant Disease, *Neuroimaging Clinics of North America.* 2000;10(3):535-545.
3. Murphy KJ, Fessler R. Vertebroplasty: a state of the art review. *Neurosurgery Quarterly.* 2001 Summer.
4. Li KW, Haroun RI, Clatterbuck RE, Murphy KJ, Rigamonti D. Superficial siderosis associated with multiple cavernous malformations: report of three cases. *Neurosurgery.* 2001 May; 48(5):1147-50 and accompanied editorial pp 1150-1. Review.
5. Murphy KJ. Multidetector CT and CTA: changes in patient and CTA: changes in patient management. *Toshiba Medical Review.* 2002 Jul.
6. Murphy KJ. Multidetector CT and CTA: changes in acute stroke. *Toshiba Medical Review.* 2002 Aug.
7. Murphy KJ. Multidetector Helical CT guided spine interventions. *Toshiba Medical Review.* 2002 Sep.
8. Murphy KJ. MultidetectorHelical MDCT in the neurointensive care setting. *Toshiba Medical Review.* 2002 Oct.
9. Obrey R, Murphy KJ. Multidetector CTA in acute stroke. *Diagnostic Imaging.* 2002 Nov.
10. Obrey R, Murphy KJ. CT fluoroscopy and Neurointervention. *Diagnostic Imaging.* 2002 Dec.
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*Letters*

1. Gailloud P, Murphy KJ. Rupture of cerebral aneurysm during angiography: Letter to the Editor, *New England Journal of Medicine.* 1999; 340(18):1442.
2. Tamargo RJ, Rigamonti D, Murphy KJ, Gailloud P, Conway JE, Clatterbuck RE. Endovascular and surgical treatment of unruptured aneurysms: comparison of risks. *Annals of Neurology.* Letter to the Editor 2001; 49:682-684.

*Book Chapters*

1. "Human anatomy brought to life; The Living Brain": Radiation Science. Uses in Medical Imaging and Therapy. Paul L. Carson PhD (ed.) ISBN 0-7872-0817-5, 1995. American College of Radiology, Radiology Centennial Radiation Science Project.
2. "Human anatomy brought to life; The Spine". Radiation Science. Uses in Medical Imaging and Therapy. Paul L. Carson PhD (ed.) ISBN 0-7872-0817-5, 1995. American College of Radiology, Radiology Centennial Radiation Science Project. This was a multifaceted interactive project composed of video, text, and computer programs aimed at the teaching of physics through radiology.
3. "Percutaneous diagnostic biopsy techniques for tumors of the spine and peripheral nerves" in Spinal cord and spinal column tumors principles and practice edited by Dickman, Fehlings Gokaslan published by Thieme 2003.

*Inventions, Patents, Copyrights*

*Awarded*

- Aug., 2001    Method and Apparatus for Strengthening Vertebral Bodies. US 6,273,916  
Sep., 2002    Co axial Biopsy Gun for obtaining tissue from a hard substance. US 6,450,973  
Dec., 2002    Needle Control Device for reducing radiation exposure. US 6,488,667  
July, 2003    A CSF shunt for chronic obstructive hydrocephalus, with access ports to allow in situ repair of obstructions, and telemetric pressure monitoring valve mechanism located on the chest wall. This patent represents the application of interventional neuroradiology catheter technology to ventriculo peritoneal shunt design. US 6,585,677

*Patient Pending*

- June, 2003    Simulation System for Medical Procedures

*Extramural Sponsorships*

*Grants*

*Current*

- 2001-2005    Co-investigator (2% effort), American Heart Association (02701755N) The inflammatory hypothesis of cerebral vasospasm, leucocytes as mediators and therapeutic targets. (Dr. R. Tamargo, Principle Investigator)  
**\$400,000**
- 2003    Co-investigator (5% effort), RO1 NS 42607-01A2: Induced hypertension in acute ischemic stroke, An RO1 submission to the National Institute of Neurologic Disease (NINDS)  
**\$811,936**
- 2003-2005    Principle Investigator (10% effort), Training Grant for Fellowship in Interventional Neuroradiology, given by American Society of Interventional Neuroradiology and American Association on Neurosurgeons (section of Cerebrovascular Disease Endovascular Surgical)  
**\$100,000**
- 2004-2005    Co-Investigator (1% effort), Cordis Neurovascular: A Feasibility Study of the Cordis Neurovascular Self-Expanding Stent System to Facilitate Endovascular Coil Embolization of Wide Neck Saccular Intracranial Artery Aneurysms.  
**\$9,000**

|                 |  |
|-----------------|--|
| 2004-2006       | National, Principal Investigator (12% effort), <b>Cook, Inc.</b> : Vertebral Fracture Stabilization with Vertifix™ Radiopaque Bone Cement plus Radiation Therapy vs. Radiation Therapy Alone for Pain Relief in Pathologic Metastatic Vertebral Fractures.<br><b>\$100,000</b>                                       |
| 2004-2006       | Johns Hopkins Site, Principle Investigator (5% effort), <b>CoAxia, Inc.</b> : A Clinical Study of Perfusion Augmentation in Acute Ischemic Stroke Using NeuroFlo™ Technology. And A Neurological Imaging Study of Acute Ischemic Stroke Subjects Between 6-12 Hours of Symptom Onset.<br><b>\$30,000</b>             |
| 2005-2008       | Johns Hopkins Site Principal Investigator (5% effort), <b>National Institutes of Health</b> : R01 NS39512 Familial Intracranial Aneurysm Study.<br><b>\$161,876</b>  |
| <i>Pending</i>  |  |
| 2004-2006       | Co-Investigator (2% effort): <b>American Heart Association</b> Beginning Grant-in-Aid. Long-term Cerebrovascular Outcome Following the Blalock-Taussig Shunt and Total Cardiac Repair.<br><b>\$125,000</b>   |
| 2004-2008       | International Principal Investigator (U.S. and Europe) (10% effort): Osteoporotic Spine Intervention Registry (OSIR). A multi-site registry to compare the safety and efficacy of Percutaneous Vertebroplasty and Kyphoplasty for treatment of osteoporotic fracture(s).<br><b>\$1,680,000</b>                       |
| 2005-2006       | Principal Investigator (7% effort), <b>National Institutes of Health SBIR</b> submission 4/1/04: Ultrasound Ablation of Bone Cancer Under CT-Fluoroscopy.<br><b>\$300,000</b>  |
| 2005-2007       | Principal Investigator (20% effort), <b>National Institutes of Health R21</b> submission 2/1/04: Novel Therapy for ICH: Minimally Invasive Intervention.<br><b>\$275,000</b>   |
| 2005-2007       | Principal Investigator (15% effort), <b>National Institutes of Health R21</b> submission 2/1/04: Analysis of Color Mapped Unenhanced Head CT in Stroke.<br><b>\$275,000</b>  |
| 2005-2010       | Principal Investigator, (15% effort) <b>National Institutes of Health Quantum Project: Technology-based Advances in Healthcare</b> submission 1/9/04: Image Guided Therapy of Vertebral Benign and Malignant Disease.<br><b>\$1,250,000</b>  |
| 2005-2010       | Principal Investigator, (15% effort) <b>National Institutes of Health Quantum Project: Technology-based Advances in Healthcare</b> submission 1/9/04: Acute Intervention Centers - a modular franchise concept for the collaborative multidisciplinary treatment of acute MI and acute Stroke.<br><b>\$1,250,000</b> |
| <i>Previous</i> |  |
| 1996-1997       | Co-Investigator, FDA Protocol 204-07 Phase 3 Levovist study. A phase 3 study of the safety, subject acceptance, and efficacy of Levovist injection (a Galactose  |

based microbubble preparation) in subjects with inconclusive arterial Doppler Sonographic examination and use in transcranial ultrasound.

\$15,000

- 1997-2001 Medical Project Leader of the European Phase 2 Multicenter Trial of the new Cook Detach-18 detachable platinum coil. This coil is designed for neuroradiological embolizations in the arterial and venous circulations. The study was carried out at 8 major European Neurointerventional centers, including the University of Geneva, Hopital Lariboisere Paris, the University of Wurtzburg, Hospital General De Cataluna, Barcelóna, and The Radcliffe Infirmary, Oxford. Based on this study, FDA approval and CE marking was obtained.  
Clinical Funding: \$5,000,000
- 1998-2001 Co-Investigator, National Science Foundation: PR 97M508 Anti-CD 18 monoclonal antibody for the treatment of vasospasm caused by subarachanoid hemorrhage in primates. (Dr. R. Tamargo, Principal Investigator)  
\$300,000
- 2001-2003 Co-Investigator, National Institutes of Health, Shared Instrumentation Grant: IS10RR015721-01 Cardiovascular Animal Research X-Ray Imaging System.  
\$500,000

**Contracts**

- 2000-present Principle Investigator (20% effort), Center for Image Guided Therapy Center (CIGT). Establishment of the CIGT as a place for collegial interactions of all image-guided therapists, to encourage cross-fertilization of ideas and techniques, and collaboration for research and educational activities.  
-Two 16-slice multidetector CT scanners (Bayview, Nelson B-100, Johns Hopkins Hospital)  
-One 4-slice multidetector CT scanner adjacent to the Meyer Neurointensive Care Unit, (Johns Hopkins Hospital)  
-One biplane neuroradiology angiography suite (Nelson B-100, Johns Hopkins Hospital)  
-Two single plane angiography suites (CIGT Traylor 3, Johns Hopkins University School of Medicine)

Direct research support: \$ 360,000

Capital Equipment support: \$8,000,000

There are areas of ongoing research in collaboration with Toshiba which include but are not limited to:

1. Research and development of a flat panel detector for angiography imaging.
2. Research and development of CT fluoroscopy in interventional neuroradiology, intracranial direct puncture interventions, radiofrequency ablation and intracranial navigation.
3. Six sigma work flow analysis of radiology and the implications in machine and software design for radiology and cardiology.

4. Process improvement in radiology and cardiology, and analysis of the benefit of MDCT in the ER in acute coronary syndrome and acute stroke, as evidenced by decrease in hospital stay.
5. Creation of an international users group based in Berlin, Germany, Leiden, Holland, Fujita, Japan and Baltimore, MD. We will all have the same equipment simultaneously, and collaborate via secure web servers and biannual meetings. This group will focus on Multidetector CT development for the investigation of acute stroke and acute coronary syndromes.
6. Establishment of the CIGT as a place for collegial interactions of all image-guided therapists, to encourage cross-fertilization of ideas and techniques, and collaboration for research and educational activities.

**IRB Approved Studies**

|           |   |
|-----------|---|
| 2000      | Detach-18 coil for endovascular intracranial vascular embolization.<br>IRB approval was terminated when FDA approval was obtained for the device.   |
| 1998-2001 | Vertebroplasty- The augmentation of fractured vertebral bodies with orthopedic bone cement in benign and malignant disease. We discontinued the IRB approval as this procedure has now become the standard of care nationally   |
| 1999-2001 | ISAT, the International Subarachnoid Aneurysm Trial, in which patients with subarachnoid hemorrhage are randomized to endovascular coiling versus open surgical clipping. Drs Rigamonti and Tamargo were co-investigators. There were 44 centers in Europe and Canada, with over 2,134 patients were enrolled. Enrollment has been stopped and patient follow up is now ongoing for 5 years. The first report has been published in the Lancet (2002 ;360:1267-74.) |
| 2004      | Boston Scientific Humanitarian Use Device: Neuroform™ Microdelivery Stent. IRB approval for HDE.  |

**EDUCATIONAL ACTIVITIES**

**Teaching**

**University of Michigan:**

|           |  |
|-----------|--|
| 1995      | Neurology Grand Rounds "The Neuroradiology of the HIV positive patient."                           |
| 1995-1996 | MRI Physics Lecturer to M3 Students as part of the radiology Curriculum                            |
| 1995-1996 | Coordinator, Neuroradiology- teaching case conference each Tuesday morning for radiology residents |

**Johns Hopkins University School of Medicine:**

|              |   |
|--------------|---|
| 1999-present | Weekly Neurovascular Conference<br>A multidisciplinary discussion of neurovascular cases, with consensus based treatment attended by Neurology, Neurosurgery, and Interventional Neuroradiology and neurointensive care. This is 1 hour of CME credit per week. |
| 1999         | Radiology Grand Rounds: "Interventional Neuroradiology: Team solutions to clinical problems."   |
| 2000         | The Conjoint Rounds Conference Hurd Hall "Vertebroplasty in Benign and Malignant Disease."  |

2001 Radiology Grand Rounds "A multidisciplinary approach to Interventional Neuroradiology."  
2001 CVDL Fellow Lecture Series "Vertebroplasty and Carotid Stenting"  
2001 Neuroradiology Fellow Lecture Series "Carotid Stenting."  
2001 Neurosurgical Grand Rounds "A multidisciplinary approach to Interventional Neuroradiology"  
2001 Johns Hopkins Neuroradiology Review Course "Spine interventions."  
2001 Howard County Hospital Grand Rounds "A multidisciplinary approach to Interventional Neuroradiology."  
2002 Radiology Grand Rounds "Multidetector CT in Interventional Neuroradiology"  
2002 Johns Hopkins Neuroradiology Review Course "Management of intracranial Aneurysms."  
2002 CVDL Fellow Lecture Series topic "Vertebroplasty."  
2002 CVDL Fellow lecture series topic "Carotid stenting."  
2002 Radiology Resident Research Initiative 'The intellectual joy of clinical research.'  
2003 Town Hall Meeting "Research Report: Drug and Stent Therapy for Arterial Blockage — A Newsweek 'Top Ten Innovation' for 2003."

**International and National CME Accredited Conferences:**

1998 1<sup>st</sup> North American Vertebroplasty Conference, Sundance Resort, Utah  
Course Director  
1999 2<sup>nd</sup> North American Vertebroplasty Conference, Sundance Resort, Utah  
Course Director  
1999-2000 "Hands on Vertebroplasty" Training Course by JHMI and the University of Maryland (4 courses in 1999, 1 in 2000)  
1999 "Hands on Vertebroplasty" Training Course by Tampa General Hospital, the University of Virginia, and Emory University (3 courses in 1999, 2 in 2000)  
2000 The Johns Hopkins International Vertebroplasty Conference, Mont Tremblant, Canada  
Course Director  
2000 The Johns Hopkins International Carotid Stenting Conference at Mont Tremblant Canada  
Course Director  
This was the first international meeting on carotid stenting and cerebral revascularization with hands on training and teaching by international faculty.  
2000 "Hands on Vertebroplasty training course" at the Annual Society of Cardiovascular Interventional Radiologists (SCVIR) meeting San Diego, CA.  
Teaching Faculty  
2001 "Hands on Vertebroplasty training course" at the Annual Society of Cardiovascular Interventional Radiologists SCVIR meeting San Antonio, TX.  
Teaching Faculty  
2001 Workshop on "Carotid Stent and Cerebral Revascularization" Hands on Workshops, American Society of Neuroradiology (ASNR) Meeting, Boston, MA.  
Course Director

- 2000 "Carotid Stent and Cerebral revascularization" Hands on Workshops, Annual Society of Cardiovascular Interventional Radiologists (SCVIR).meeting, Baltimore, MD  
Course Director
- 2001 "Cerebrovascular Emergencies". Johns Hopkins Medicine, Baltimore, MD  
Course Director
- 2002-present Center for Image Guided Therapy Training (CIGT) at Johns Hopkins University, School of Medicine.  
Course Director  
A two-day hands on training courses for 6 attendees on Vertebroplasty.  
(6 courses in 2002, 9 courses in 2003 and 6 courses in 2004)
- 2002-2003 "Stroke Thrombolysis and Carotid Stent" training course jointly run through the Society of Interventional radiology (SIR) American and the Society of Interventional Therapeutic Neuroradiology (ASITN).  
The aim of this course is to teach large numbers of radiologists in the skills needed to treat acute stroke. This course will be conducted in both the Dotter Institute, Oregon Hospital State University (OHSU) Portland, OR and the Center for Image guided Therapy (CIGT), Johns Hopkins University School of Medicine, Baltimore, MD.  
Course Director (5 courses in 2002, 2 courses in 2003)
- 2003 "Carotid Stent and Cerebral Revascularization" and "Vertebroplasty" Hands on Workshops, Annual Society of Cardiovascular Interventional Radiologists (SCVIR) Meeting, Salt Lake City, UT.  
Course Director
- 2004 "The Equinox Seminar. Stenting Coiling and Catheters: Evolution or Natural Selection? Sharing Knowledge." The aim of this course is to discuss issues related to image-guided therapy with cardiologists, vascular surgeons, neurosurgeons and radiologists to build negotiation skills and dialogue.  
Course Director
- Mentoring**
- Neurointerventional Fellowship Training*
- 1998 Phillip Gailloud, M.D.  
Current position: Interventional Neuroradiologist, Assistant Professor of Radiology, Johns Hopkins University
- 2001 Donald Heck, M.D.  
Current Position, Interventional Neuroradiologist, Salem, NC.
- 2002 Jeffery Carpenter, M.D.  
Current Position: Interventional Neuroradiologist. Director of Neuroradiology, University of West Virginia, Morgantown, WV.
- 2003 Baljit Deol, M.D.  
Future Position: Interventional Neuroradiologist, position pending.
- 2003 Jacob Agris, M.D.  
Future Position: Director of Interventional Neuroradiology, Richmond, VA.

**Editorial Activities**  
*Journal Peer Reviewer*

1999-present Reviewer, American Journal of Neuroradiology  
2000-present Reviewer, Radiographics  
2001-present Reviewer, Annals of Neurology  
2000-present Reviewer, Radiology  
2002-present Reviewer, Ultrasound in Obstetrics and Gynecology

*Scientific Meeting Reviewer*

1998-present Radiology Society of North America for RadioGraphics

**CLINICAL ACTIVITIES**

1998-present Director of Interventional Neuroradiology, Johns Hopkins University  
We perform approximately 2,500 exams per year. We perform 7-10 Interventional Neuroradiology cases and 30 diagnostic cerebral angiograms per week.  
Interventions include spine, vertebroplasty, and intraoperative angiography. We have increased the number of procedures by 300% over the past 4 years. We have 9 dedicated interventional neuroradiology X-ray technologists and 4 nurses.

**Specialty Certifications**

**Medical License**

Maryland: D0054096

Michigan: expired

New York: expired

**Certifications**

1994 Board Certification in Radiology

1994 Fellow of the Royal College of Physicians of Canada, June 1994 (FRCPC)

1997 Certificate of added qualification (CAQ) in Neuroradiology

**Organizational Activities**

**Intradepartmental Committees and Administrative Service**

2001 Committee member for the interventional and therapeutic component of the Department of radiology  
2002 Member of Oversight Committee for the Center for Image Guided Therapy (CIGT)  
2002 Iceland: I have worked for 18 months to develop a relationship with the Icelandic government, to transfer neurovascular patients to JHH for treatment. I visited Iceland on December 19-20, with a member of the international office for 2 days of negotiation and to deliver CME educational lectures on neurovascular topics. This will benefit all the neuroscience group. These patients will be transferred to JHH.  
2003 Johns Hopkins Bayview Medical Center: Our service expanded to Bayview in November, 2003 and supply 1/5 of an FTE there as well as continue preexisting call coverage.

- 2003 **GBMC** Over the past year I have developed excellent relationships with GBMC physicians. We began our interventional oncology service there on March 17<sup>th</sup>. They will pay us \$200,000 per year for one day a week service. All other patients will be transferred to JHH.
- 2003 **Future: Penn State Medical Center at Hershey** Over the past 2 year I have developed excellent relationships with Penn state physicians. In late 2002 we will begin a service there. They will pay us \$175,000 per year for one day a week service. All other patients will be transferred to JHH.

**Interdepartmental Committees**

- 1997-1998 Chairman of MRI Process Improvement, Department of Radiology, Albany Medical Center, Albany, New York
- 2000 Member of the Vasculitis Group, Johns Hopkins Medicine.
- 2000-present Multidisciplinary center of excellence for ischemic brain injury and neurovascular disease, working group member Johns Hopkins Medicine.
- 2000-present Hydrocephalus Working Group member, we aim to develop a center of excellence for management of normal pressure hydrocephalus of dementia with Dr. Michael Williams, Dept. Neurology, and Dr. Daniele Rigamonti, Dept. Neurosurgery.
- 2001 Neurovascular center marketing effort Coordination with Dr. Eric Aldrich of the effort which involves Neurosurgery/neurology/NCCU and INR
- 2003 The Johns Hopkins Heart and Vascular Institute Organization group. Member of the Integration of services (building and planning), and Fund raising/Development group.
- 2003-present Member of Committee to establish the Center for Cerebrovascular Disease and obtain designation as a Primary Comprehensive Stroke Center by JCAHO and the state.

**Professional Societies**

*Memberships*

- 1988 Medical Director, CHI, Community Health International (a Irish based non-government aid organization)
- 1991–present Radiological Society of North America (RSNA)
- 1991–present American Roentgen Ray Society (ARRS)
- 1994– 1997 Junior Member: American Society of Neuroradiology (ASNR)
- 1997– present Senior Member American Society of Neuroradiology (ASNR)
- 1997– present American Society of Interventional & Therapeutic Neuroradiology (ASITN)
- 1998–present Society of Cardiovascular and Interventional Neuroradiology (SCVIR).
- 2000–present The American Society of Spine Radiologists (ASSR)
- 2000–present Council member, The American Heart Association Council on Stroke

*Offices and Positions*

- 1994-1995 American College of Radiology Centennial School Education Committee Member

- 2002 SCVIR Advisory Panel Member to the FDA on Stroke and Cerebral Revascularization.
- 2002 Guest Speaker on Capitol Hill on behalf of The American Heart Association, American Society of Interventional Therapeutic Neuroradiology and the American Society of Neuroradiology in support of the STOP legislation. If this legislation is passed, 450 Million dollars will be made available for patient education on stroke.
- 2002 Invited speaker to the FDA in-house educational symposium on vertebroplasty and cerebral revascularization
- 2002 Invited speaker to the FDA symposium on anticoagulation, antiplatelets, and thrombolytic therapies.
- 2002-2003 Course Director of the Society of Interventional Radiology (SIR) and American Society of Interventional Therapeutic (ASITN) Radiology Training Programs on cerebral revascularization and carotid stenting.
- 2003-2004 Course Director of the Society of Interventional Radiology (SIR) and American Society of Interventional Therapeutic (ASITN) Radiology Training Programs on cerebral revascularization and carotid stenting.

## **RECOGNITION**

### **Undergraduate Honors and Awards**

- 1984 Gold Medal in Medicine and Surgery, Royal College of Surgeons, Dublin, Ireland
- 1985 Honors in Psychiatry, Obstetrics, Gynecology, ENT and Ophthalmology.
- 1986 J. J. Fitzsimmons Gold Medal for Internal Medicine Royal College of Surgeons, Dublin, Ireland
- 1986 Gold Medal in Surgery, Royal College of Surgeons, Dublin, Ireland.
- 1986 Gold Medal in Medicine James Connolly Memorial Hospital.
- 1986 Gold Medal and McDonnell Prize in Surgery, The Charitable Infirmary, Dublin, Ireland.

### **Postgraduate Honors and Awards**

- 1988 Joint 1<sup>st</sup> Place, B.Sc. in Anatomy, Embryology and Physical Anthropology, University College, Dublin, Ireland
- 1996 Roentgen Fellow Outstanding Research Award, Radiological Society of North America (RSNA).
- 1998 Prix du jubilé - Société Suisse de Radiologie Médicale, Modèles in vitro de fistules artérioveineuses intracrâniennes pour l'évaluation de nouveaux matériaux de traitement endovasculaire. Gailloud P, Muster M, Murphy, KJ, Mottu F, Piotin M, Mandai S, Fasel JHD, Rüfenach, DA.

### **Invited Talks**

#### *National*

1. MR Angiography at Low Field/Open MR. Key speaker at the Open MRI Conference, Hilton Head, August 28, 1998.

2. "The Future of Low Field MR." Key speaker at the Open MRI Conference, Hilton Head, August 28, 1998.
3. "Vertebroplasty" Key Speaker at the Northeastern Vascular Interventional Radiologist Technologist Annual Meeting, Buffalo, NY, October 16, 1998.
4. "Vertebroplasty" Key Speaker at the Mid America Interventional Radiology Society Annual Meeting, Kansas City, April 10, 1999.
5. "Extracranial Embolization" Key Speaker at The Mid-America Interventional Radiology Society Annual Meeting, Kansas City, April 10, 1999.
6. "Managing a Gadolinium Contrast Reaction" Key Speaker at the Open MRI Conference, Las Vegas, March 31, 1999.
7. "Dealing with a Gadolinium Contrast Reaction" Key Speaker at the Open MRI Conference, Las Vegas, March 31, 1999.
8. "The Future of Open MR Imaging" Key Speaker at the Open MRI Conference, Las Vegas, March 31, 1999.
9. "Neurointervention" Speaker at the Sixth Annual University of Pennsylvania Conference on Interventional Radiology, Wye River, May 23, 1999.
10. Hopkins on the Road Lectures at Montgomery General Hospital, "Interventional Neuroradiology", 1999
11. "Vertebroplasty in benign and malignant disease". Chesapeake Bay Radiological Society, Speaker. August 26, 1999.
12. Neuroradiology Review Course, The Johns Hopkins University School of Medicine, Speaker, Baltimore, September 30, 1999.
13. Mid American Interventional Radiology Society Meeting, Springfield, October 19, 1999.
14. Hopkins On The Road Lecture, "Acute Stroke Management as a Multidisciplinary Team" at Frederick Memorial Hospital, Frederick, MD, November 12, 1999.
15. Hopkins On The Road Lecture, "Acute Stroke Management as a Multidisciplinary Team" at Doctors Community Hospital, Lanham, MD, December 2, 1999.
16. Hopkins On The Road Lecture, "Endovascular Treatment of Intracranial Neurovascular Disease" Harbor Hospital, Baltimore, December 3, 1999.
17. American Association of Neurosurgeons (AANS) Annual Meeting, "Cavernous Malformation" Key Speaker, February 2000.
18. "Vertebroplasty in the relief of severe pain after osteoporotic fracture". Johns Hopkins Pain Anesthesia Conference, Baltimore MD 8/25-26/2000.
19. Vertebroplasty in Benign and Malignant Disease. The American Association of Interventional Radiology Technologists Meeting, Rochester, NY, September, 2000.
20. Howard County Hospital Grand Rounds, November, 2001
21. "Carotid Stenting" St Agnes Hospital Cardiovascular Research Day Guest Speaker, Nov 2001
22. Guest speaker, "Multidetector CT in Neurointervention" The Stanford Multidetector CT Conference, San Francisco, June 2001.
23. Guest speaker "Carotid stenting, does it approach endarterectomy in patient benefit" The Stanford Current Updates in Interventional Radiology Meeting, Tahoe CA Feb 15<sup>th</sup> 2002.
24. Guest Speaker SVCIR 2002 "Embolization of epistaxis" April 2002
25. Guest speaker "Multidetector CT in neurointervention" The Stanford. Multidetector CT Meeting, San Francisco, June 21<sup>st</sup> 2002

26. Guest speaker "Stroke intervention and cerebral revascularization" The Stanford Current Updates in Interventional Radiology Meeting, Tahoe CA Feb 15<sup>th</sup> 2003.
27. Guest speaker "CT perfusion and acute stroke imaging" The Stanford Current Updates in Multidetector CT Meeting, San Francisco June 2003.

*International*

1. Murphy KJ, Wu VW, Miller M, Burke MJ. "Computer assisted instruction in computerized tomography of the abdomen and pelvis in the emergency room patient". Japanese Radiological Society Meeting, April 1993.
2. Murphy KJ, Line, BR, Malfetano, J. "Etidronate Disodium decreases the sensitivity of Tc-99m bone scanning" Society of Nuclear Medicine 40th Annual Meeting, Toronto, June 1993.
3. Murphy KJ, Wu VW, Miller M, Burke MJ. "Computer assisted instruction in computerized tomography of the abdomen and pelvis in the emergency room patient". Societe Francais de Radiologie et D'imagerie Medicale Paris, November 1994.
4. Murphy KJ. "Computer assisted instruction in computerized tomography of the emergency room patient". European Congress of Radiology, Vienna, March 1995.
5. Murphy KJ. MR Angiography "Its A Good Thing" Neurosciences Meeting at Beaumont Hospital, The Royal College of Surgeons in Ireland. June 1996.
6. Murphy KJ. "Primary Health Care for Refugees and the Role of the Graduate Physician" The Royal College of Surgeons in Ireland, June 1996.
7. Murphy KJ, Mandai S, Gailloud P, Muster M, Fasel JH, Rüfenacht DA. "In vitro evaluation of the behavior of new J-shaped mechanical detachable coils in a model of a dural arteriovenous fistula of the transverse sinus". Val D'Isère France, The WIN International Interventional Neuroradiology Meeting, January 1997.
8. Murphy KJ, Mandai S, Gailloud P, Muster M, Fasel JH, Rüfenacht DA. "In-vitro studies to define the term "dense packing" of aneurysms with detachable platinum coils". Val D'Isère France, The WIN Interventional Neuroradiology meeting, January 1997.
9. "Management of severe vasospasm in patient with an untreated MCA aneurysm". Val D'Isère France, The WIN Interventional Neuroradiology meeting January 1997.
10. "Management of active subarachnoid bleeding on diagnostic angiography with GDC coiling". Val D'Isère France, The WIN International Interventional Neuroradiology meeting, January 1997.
11. Guest Speaker "Flow assisted microcatheter manipulation in interventional neuroradiology". University of Fribourg Germany, June 13, 1997.
12. Guest speaker "The role of vertebroplasty in the management of osteoporosis". The American Society of Bone and Mineral Research, Toronto, September 22, 2000.
13. Key Speaker on "Vertebroplasty" Japanese Society of Interventional Neuroradiology, May 18, 2001
14. Key Speaker at the Indian Society of Interventional Neuroradiology Trivandrum, India, February 20-25, 2001
15. Guest Speaker, "Vertebroplasty in benign and malignant disease". The Royal Australian and New Zealand College of Radiology 52nd Annual Meeting Melbourne, Australia, October, 2001

16. Guest Speaker, The Japanese Congress of Radiology Meeting Fujita, Japan, November, 2001
17. Guest speaker, "Vertebroplasty in benign and malignant disease," "Carotid stenting, how does it compete with the gold standard". The Sobrice Meeting, Rio De Janeiro, Brazil Nov, 2001
18. Guest speaker, The Munich Multidetector CT meeting April 18-19,2002
19. Session speaker, "Multidetector CT in neurointervention" American Society of Neuroradiology 2002 Vancouver, Canada
20. Guest Speaker, "Multidetector CT in neurointervention" The Royal Australian and New Zealand College of Radiology 53rd annual meeting Adelaide, Australia October, 2002
21. Guest Speaker, Dural AV Fistulas, new management options" The Italian Society of Neuroradiology May 16, 2003
22. Guest Speaker, "Vertebroplasty in benign and malignant disease" The Italian Society of Neuroradiology, Verona, Italy, May 16, 2003.

**Visiting Professorships**

- |      |   |
|------|---|
| 1999 | Visiting Professor New Delhi teaching vertebroplasty and endovascular techniques. February                        |
| 2000 | Visiting Professor at University of Toronto, and McMaster University, Ontario, Canada January 10-12               |
| 2000 | Visiting Professor Seoul South Korea, September 24-29   |
| 2000 | Visiting Professor New Delhi, and Bombay, India, Teaching Vertebroplasty, and endovascular technique, February.   |
| 2001 | Visiting Professor Beijing Neurologic Institute, Ghuanghou, Harbin, Shanghai, and Hong Kong, China, January 3-12. |
| 2001 | Visiting Professor Madras Medical College, Madras India, and Vellore Medical College, February 20-25.             |
| 2002 | Visiting Professor in Melbourne, Adelaide, and Sydney October   |
| 2002 | Visiting Professor McMaster University, Hamilton Ontario, Canada, March 11-15.                                    |
| 2002 | Visiting Professor Vancouver General Hospital, May.   |
| 2002 | Visiting Professor Royal Perth Hospital, Perth, Australia, October.   |
| 2003 | Visiting Professor Beijing Neurologic Institute, China, March 9-12.   |

**Voluntary International Medical and Educational Activity**

- |              |   |
|--------------|---|
| 1983         | Ladakh, Northern India worked and educated "bare foot" doctors in a Tibetan Refugee Camp.   |
| 1985         | Started a Primary Health Care Project and educated "bare foot" doctors in Ganden Monastery, in a Tibetan Refugee camp in Southern India.          |
| 1986         | One month in Peru doing primary health care, educating "bare foot" doctors, working in prisons.   |
| 1988         | Started a primary school for Tibetan refugees in Bodhanath, Kathmandu, Nepal.   |
| 1996         | Returned to Kathmandu to support the school and for primary health care education. Visiting professor at Tribhuvan University Hospital Kathmandu. |
| 1997-present | Continued financial support of the primary school and the primary health care center.   |

**Alternative Media**

1. Developed website for patients with access to information on stroke and vertebroplasty  
www.brainavm.net and www vertebralfracture.org
2. Afternoon Drive, "Johns Hopkins Medical Minute on detachable coils for aneurysms"  
December 8, 1998, Tuesday, PM (ET), WBBR-AM Radio
3. News 4 This Morning, " Bone Cement" November 12, 1998, Thursday, 6:00 A.M.,  
WFOR-TV, Television
4. News Four This Morning," Doctors at Johns Hopkins Medical Center in Baltimore are  
using glue to fix fractures in the spine" November 12, 2998, Thursday, AM (MT), KCNC-  
TV, Television
5. Eyewitness News, " New glue which cements bone together" November 12, 1998,  
Thursday, AM, KPIX-TV, Television
6. Channel Two News at Noon, " There is a new superglue that fixes fractures" November 12,  
1998, Thursday, 12:00 PM, WCBS-TV, Television
7. Eyewitness News Update, November 11, 1998, Wednesday, 11:00 PM, KDKA-TV,  
Television
8. News 3, November 11, 1998, Wednesday, PM, KYW-TV, Television
9. CBS 2 News at Eleven, November 11, 1998, Wednesday, 11:00 PM (PT), KCBS-TV,  
Television
10. Eyewitness News, November 11, 1998, Wednesday, PM, WJZ-TV, Television
11. Biotech Week, August 8, 2001, EXPANDED REPORTING; Pg. 24, 390 words, TOSHIBA  
CORP. MEDICAL SYSTEMS CO.; Joint Research Program, Training Center, For  
Interventional Radiology Formed
12. Pain & Central Nervous System Week, April 29, 2002, EDITOR'S CHOICE; Pg. 9, 491  
words, SURGERY: Cognitive testing reduces risks of procedure for brain arteriovenous  
malformations.
13. Medical Devices & Surgical Technology Week, December 1, 2002, EDITOR'S CHOICE;  
Pg 2, 506 words, ANEURYSM: Brain coils slash death, disability
14. Pain & Central Nervous System Week, November 25, 2002, EDITOR'S CHOICE; Pg. 5,  
505 words, ANEURYSM: Brain coils slash death disability.
15. Internet Wire, October 29, 2002 Tuesday, 561 words, Reducing The Risk of Death and  
Disability from Ruptured Brain Aneurysms; New Study Sheds Light on Coiling Treatment,  
October 29, 2002, Englewood, Co; Internet Wire.
16. UNITED PRESS INTERNATIONAL, JUNE 10, 2002, Monday, ENTERTAINMENT, 708  
words, Health Tips, by Lida Wasowicz, UPI Senior Science Writer.
17. The Baltimore Sun, December 9, 2002 Monday, FINAL Edition, Pg. 1A, 1824 words,  
Promising Stroke Therapy may be held up in debates; Drugs dissolves clots; some worry  
it's too risky, Diana K. Sugg.
18. Newsday (New York, NY), October 26m 2002 Saturday, ALL EDITIONS, Pg. A19, 373  
words, Method to Treat Aneurysms, by Jamie Talan, (staff writer).
19. The Baltimore Sun, October 25, 2002, Friday, FINAL edition, Pg. 3, 727 words, Progress  
in Aneurysm Treatment; Inserting platinum coils often more effective than using clips,  
study shows, Jonathan Bor.

20. The New York Times, November 12, 2002, Tuesday, Late Edition – Final, Section F; Page 5; Column 2; Health & Fitness, 1579 words, "Fixing Aneurysms without Surgery," by Donald G. McNeil, Jr.
21. Newsweek, December 8, 2003, Page 86, "To Save the Stricken Brain, " part of the "Health 2003: The Top Ten" section beginning on Page 61 by Andrew Murr.

**(12) APPENDIX C – RELATED PROCEEDINGS**

There are no Related Proceedings (pending or decided appeals or interferences) identified pursuant to 37 CFR 41.37(c)(1)(ii), hence there is no decision for inclusion in this Brief pursuant to 37 CFR 41.37(c)(1)(x).